

### **REMARKS**

The original application was filed with Claims 1-56. Claims 1-17 and 34-56 were cancelled in a Preliminary Amendment filed on October 4, 2001. Claims 57 – 65 were added to the application in the same Preliminary Amendment. Claims 57 – 65 are now withdrawn from consideration in the present application as directed to a non-elected invention. Claims 18 – 33 are currently pending and at issue. Of the claims remaining, Claims 18 and 27 have been amended to address non-substantive issues.

Claims 18 -33 stand initially rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 3,780,308 to Nablo (hereinafter “Nablo”). Applicants respectfully traverse the rejection and request reconsideration in light of the arguments set forth below.

Claim 18, the sole pending independent claim under consideration, is directed to a method for sterile filling a container with a sterile fluid. The amended claim and its dependents require the step of introducing a filling port of the container into an active sterile field, then transferring an aliquot of the sterile fluid into the container through the filling port “while in the active sterile field.” It is only after the filling of the container that the filling port is removed from the sterile field.

Nablo discloses an aseptic filling process and apparatus. Specifically, Nablo discloses a surface sterilization process for packaging articles or containers **7**. The containers **7**, as shown in Figures 5a and 5b, are irradiated under sterilizing head **A** before moving to the filler spout being irradiated by dual sterilizing heads **B**. Nablo states that the “system is used to maintain the surface of the filler spout **3'** in aseptic condition while in the retracted position on each operation.” (Col. 6, lines 39-42). During the transfer of the containers **7** from head **A** to heads **B**, the container **7** is not within the active sterile field created by either sterilizing head. Instead, the container **7** is exposed to the ambient environment within irradiation zone **4** (a.k.a., working zone volume **4**, aseptic filler zone **4**, packaging zone **4**, packaging region **4**, working volume **4**, zone **4**, region **4**, and aseptic zone **4**). Nablo does not disclose this zone **4** to be an active sterile field. Quite the contrary, in fact. Nablo states “[a]septic conditions in the working volume **4** are accomplished by the use of high efficiency particle filtration of the air....” (Col. 6, lines 54-56). Nablo also discloses that the air may be sterilized by using, for example, an irradiating head “to

treat air driven into region 4 during each operation of filler head 3'." (Col. 6, lines 60-64).

Accordingly, there can be no proper assertion that Nablo discloses filling a container while maintaining the filling port of the container within an active sterile field.

Nablo discloses maintaining, in essence, the "dispensing" port of the bulk container in a sterile field. While the present invention does this as well during filling of containers, it is the filling port of the container itself which must be maintained in the active sterile field during filling of the container. Maintaining the container filling port within a purported sterile or aseptic environment is not sufficient for purposes of the present invention, and fails to properly render obvious the present claims.

This distinction is also not without significance. The medical containers subjected to the claimed processes of the present application require a Sterility Assurance Level (SAL) of  $10^{-6}$  (i.e., 1 live "bug" remaining out of 1,000,000), while food containers, such as those sterilized by the methods of Nablo, require only a SAL of  $10^{-3}$  (i.e., 1 live "bug" out of 1,000). Accordingly, maintaining the container port within the active sterile field while filling the container with a bulk fluid is an important step in the sterilization process. Nablo places a greater importance on maintaining the dispensing port of the bulk container within the field only when retracted---that is, when it is not dispensing liquid. The potential result is contamination of the container filling port, a significant undesirable occurrence for medical containers such as IV bags, drug vials, and the like.

In order to support a conclusion that a claim is directed to obvious subject matter, the cited references must impliedly suggest the invention *described by the claim*, or the Examiner must present a convincing line of reasoning as to why an artisan would have found *the claimed invention* obvious in light of the teachings of the cited references. See Ex Parte Clapp, 227 U.S.P.Q. 972 (PTO Bd. App. 1985). "[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Laskowski et. al., 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), citing, In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In discussing the mandate of 35 U.S.C. §103, the Federal Circuit holds "it is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties *and*

*the problem it solves.*”[Emphasis added]. *In re Wright*, 6 U.S.P.Q. 2d 1959 (Fed. Cir. 1988). It is not enough to just find components in the prior art.

On that point, the Federal Circuit has noted:

[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious . . . [o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

*In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). The decomposition of an invention “into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention, is a forbidden *ex post* analysis.” *Id.*

The Examiner has given no weight to the claimed limitation of transferring the bulk fluid to the container while the filling port of the container is within an active sterile field.

The Examiner has incorrectly characterized the cited reference to Nablo by stating “a filler spout is maintained in aseptic condition and the package port and filler spout are irradiated during filling with the electrons.”<sup>1</sup> As discussed previously, Nablo does not irradiate the container port during filling and, in fact, does not appear to irradiate the bulk container dispensing port during filling either. Instead, Nablo discloses irradiating the dispensing port of the bulk container when it is in a retracted position.

Accordingly, the Applicants traverse the Examiner's rejection of the pending claims. Reconsideration and withdrawal of all rejections in light of the amendments and remarks is respectfully requested.

All the remaining claims are dependent upon independent Claim 18. Each dependent claim merely adds a further limitation to this independent claim. As Claim 18 is in condition for allowance, the dependent claims should likewise be considered allowable. Accordingly,

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<sup>1</sup> Presumably, the examiner is referring to filling the container with a bulk fluid and irradiating the port and spout with the electrons.

reconsideration is respectfully requested and a notice to that effect is earnestly sought at the examiner's earliest convenience.

Applicants request that the remaining non-elected claims, Claims 57-65, be withdrawn from consideration without prejudice.

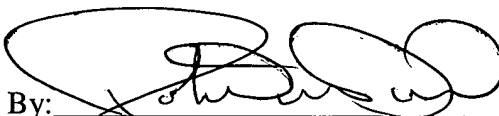
### CONCLUSION

Claim 1-56 were originally pending in the present application. Claims 1-17 and 34-56 were cancelled in a Preliminary Amendment filed on October 4, 2001. Claims 57 – 65 were added to the application in the same Preliminary Amendment. Claims 57 – 65 are now withdrawn from considerations in the present application as directed to a non-elected invention. Claims 18 – 33 are currently pending and at issue. Of these remaining claims, Claims 18 and 27 have been amended to address non-substantive issues. The Examiner has initially rejected each of these claims under 35 U.S.C. 103 and 112. Applicants have amended Claims 18 and 27 to clarify matters where necessary. In light of the amendments and the above-remarks, Applicants believe all considered claims are now in condition for allowance. Reconsideration of these claims is respectfully requested.

If it would expedite the progress of this Application through the examination process, the Examiner is authorized to call the undersigned attorney.

Respectfully submitted,

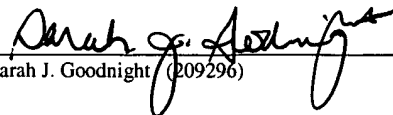
Dated: September 23, 2004

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Date of Deposit: September 23, 2004

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